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| 10/697,356 | 10/29/2003 | Kenneth F. Buechler | 071949-2705 | 7520 |

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FOLEY & LARDNER
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

| EXAMINER | |
|---|---|
| CHEU, CHANGHWA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,356 | BUECHLER, KENNETH F. | |
| | Examiner | Art Unit | |
| | Jacob Cheu | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

Claims 1-9 are rejected under the judicially created doctrine of double patenting over claims 1-10 and 17 of U. S. Patent No. US 6670196 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant invention directs to a method for determining the ratio of oxidized cardiac troponin I to reduced cardiac troponin I in a patient sample. The method comprising contacting the patient sample with a first antibody specific both oxidized and reduced troponin I, and use a second antibody specific only for one of oxidized and reduced cardiac troponin I, whereby said first and second antibodies form a complex comprising one of said oxidized or reduced cardiac troponin I , and do not from a complex comprising other of said oxidized or reduced cardiac troponin I present in the sample. The current recited claims are covered by the claims 1-10 and 17 of US Patent 6670196, particularly, claim 17 specifically recites using the similar first and second antibodies to perform similar oxidized/reduced ration troponin I binding assay.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### *Claim Rejections - 35 USC § 112*

### *Written Description*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The instant invention directs using specific antibodies detect oxidized, reduced or both forms of cardiac troponin I proteins from patient's sample. Applicant used conventional technique for screening suitable antibodies. Particularly, applicant incorporates WO 96/33415 in its entirety for the making and selection of antibodies. However, in light of the WO 96/33415 specification, the data merely support that applicant had discovered antibodies having the recited characteristics of stronger binding affinities for oxidized troponin I compared to that of reduced troponin I, ranging from 5 times, 10 times and fifty times, respectively (See page 52, Table 1). There are no data from the WO 96/33415 being reported that the antibody having a binding affinity for reduced cardiac troponin I greater than that of oxidized from 5 times, 10 times and 50 times. Applicant merely screens different clones in selection of suitable antibodies recognizing both oxidized and reduced troponin I, or specific for either oxidized or reduced form of troponin I.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 (CAFC 1993)(the compound itself is required); and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. Accordingly, claims 14-16 fail to comply with the written description requirements set forth in 35 USC, 112, first paragraph.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 9, it is not clear what is the "normalizing factor". Applicant needs to clarify.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 7, 10-13, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler et al. (WO 96/33415).

Buechler et al. teach a method for determining the ratio of oxidized cardiac troponin I to reduced cardiac troponin I in a patient. Buechler et al. teach using a first antibody that

speciically binds both oxidized and reduced cardiac troponin I, and a second antibody that specifically binds to either oxidized or reduced cardiac troponin I, whereby the first and second antibody form a complex comprising one of said oxidized or reduced cardiac troponin I present in the sample, and do not form a complex comprising the other of said oxidized or reduced cardiac troponin I present in the sample. Buechler et al. teach using immunoassay to detect the binding between oxidized, reduced, oxidized/reduced based on the signal intensities (See Example 3; page 50-52; Table 1; Example 9; Table 4).

With respect to claims 2-3, Buechler et al. teach using solid support for attachment of first and second antibodies (See Example 1).

With respect to claims 4-5, the signal for ELISA assay is fluorometeric detectable (See Example 1).

With respect to claims 11-13, the antibodies used by Buechler et al. have the characteristics of binding affinity for oxidized troponin I, 5 times, 10 times and 50 times greater than that of reduced troponin I (See Table 1).

With respect to claim 17, Buechler et al. teach that the ratio of oxidized cardiac troponin I to that of the reduced form is relating to myocardial infarction condition (See Example 9 and Table 4).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. in view of Vanderlaan et l. (US 5429925).

Buechler et al. reference has been considered but is silent in teaching use of standard curve calculated known ratios of oxidized and reduced troponin I or coupling with a factor for normalizing statistical analysis.

Vanderlaan et al. teach using stardard curve to estimate analyte and normalizing raw data for statistical analysis (Col. 12, line 14-20).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Buechler et al. with the statistical analysis, such as standard curve and normalizing analysis as taught by Vanderlaan et al. since it is well-known to use standard curve and normalizing data for analysis, and it is a routine practice in the art.

***Conclusion***

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

October 3, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/17/05